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Exhibit 455

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Case No. 12-5061

CARDINAL HEALTH, INC.,
Plaintiff-Appellant,

v.

ERIC H. HOLDER, JR., *et al.*,
Defendants-Appellees.

On appeal from the United States District Court for the District of Columbia in Case No. 1:12-cv-000185, Judge Reggie B. Walton

AMICUS CURIAE BRIEF OF HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION IN SUPPORT OF CARDINAL HEALTH, INC.'S MOTION FOR INJUNCTION PENDING APPEAL

David L. Durkin
Richard L. Frank
OLSSON FRANK WEEDA
TERMAN MATZ PC
600 New Hampshire Avenue, N.W.
Suite 500
Washington, D.C. 20037
(202) 789-1212
(202) 234-3550 (telecopy)
ddurkin@ofwlaw.com

Counsel to Movant/Proposed *Amicus Curiae*
Healthcare Distribution Management
Association

Not scheduled for Oral Argument as of the date of filing of this brief.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

As required by D.C. Circuit Rule 27(a)(4) and pursuant to D.C. Circuit Rule 28(a)(1), Movant/Proposed *Amicus Curiae* Healthcare Distribution Management Association ("HDMA") makes the following Certificate as to Parties, Rulings, and Related Cases:

Parties and Amici

The parties in the district court and this Court are:

Plaintiff-Appellant

Cardinal Health, Inc.

Defendants-Appellees

Eric H. Holder, in his official capacity as Attorney General of the United States;

United States Department of Justice;

Michele M. Leonhart, in her official capacity as Administrator of the Drug Enforcement Administration; and

Drug Enforcement Administration.

Amici

Neither the District Court nor this Court has granted any party leave to intervene or to participate as *amicus curiae* at this time. Movant/Proposed *Amicus Curiae* HDMA seeks permission to file an *amicus curiae* brief in this matter.

Rulings Under Review

The ruling under review in this case is a February 29, 2012 order (Dkt. No. 27) of the U.S. District Court for the District of Columbia (Judge Reggie B. Walton) denying Plaintiff-Appellant Cardinal Health, Inc.'s February 6, 2012 Motion for Preliminary Injunction (Dkt. No. 5), which sought to enjoin enforcement of an Immediate Suspension of Registration Order that the Drug Enforcement Administration ("DEA") signed on February 2, 2012, and served on February 3, 2012. The district court stated its reasoning orally at a hearing held on February 29 and indicated that a written opinion would be forthcoming.

Related Cases

This case has not previously been before this Court or any other court. A related case, *Cardinal Health, Inc. v. DEA*, No. 12-1126, is currently pending in this Court. Case No. 12-1126 arises from a Protective Petition for Review filed by Cardinal Health, Inc. on March 1, 2012 that seeks review of the same Immediate Suspension of Registration Order signed by DEA on February 2, 2012 that is at issue in this case. Movant/Proposed *Amicus Curiae* HDMA is neither a party nor *amicus* in that matter.

Additionally, a related case, *Holiday CVS, L.L.C. v. Holder*, et al., No. 1:12-cv-00191-RBW (D.D.C), is pending before the U.S. District Court for the District of Columbia. Movant/Proposed *Amicus Curiae* HDMA is neither a party nor *amicus* in that matter.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure, Movant/Proposed *Amicus Curiae* Healthcare Distribution Management Association does not have a parent corporation, and does not have any corporate stock.

March 7, 2012

/s/
David L. Durkin
OLSSON FRANK WEEDA TERMAN MATZ PC
600 New Hampshire Avenue, N.W.
Suite 500
Washington, D.C. 20037
(202) 789-1212
(202) 234-3550 (telecopy)
ddurkin@ofwlaw.com

Counsel to Movant/Proposed *Amicus Curiae*
Healthcare Distribution Management Association

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Certificate of Compliance With Type-Volume Limitation, Typeface Requirements, and Type Style Requirements

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 3,054 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft® Office Word 2003 in 14-point type, Times New Roman font.

/s/_____
David L. Durkin
OLSSON FRANK WEEDA TERMAN MATZ PC
600 New Hampshire Avenue, N.W.
Suite 500
Washington, D.C. 20037
(202) 789-1212
(202) 234-3550 (telecopy)
ddurkin@ofwlaw.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes and Regulations

Rules

Federal Register

Miscellaneous

Pursuant to the concurrently filed Motion for Leave To File *Amicus Curiae* Brief, Healthcare Distribution Management Association ("HDMA") respectfully submits this brief in support of plaintiff-appellant Cardinal Health, Inc.'s ("Cardinal Health") Emergency Motion for Injunction Pending Appeal.

I. STATEMENT OF INTEREST

Amicus curiae HDMA is the national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors.[1] These healthcare distributors deliver lifesaving products and services, ensuring that 300 million U.S. consumers have continuous access to prescription drugs and other important products. Prescription drugs are rarely shipped from the manufacturer straight to the pharmacy or other healthcare provider. Rather, most prescription drugs are sold by manufacturers to distributors that ensure that nine million products are safely and efficiently delivered to 200,000 pharmacies, hospitals, clinics, physician offices, nursing homes, government providers, and others each and every day.

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[1] As required by Fed. R. App. P. 29(c)(5), HDMA states that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than HDMA, its members, and its counsel contributed money that was intended to fund preparing or submitting this brief. HDMA member Cardinal Health does pay organizational dues to HDMA set by formula, but funding for this brief was provided out of general operating revenues and not by any special assessment on the membership.

HDMA has 34 distributor members. What they have in common is they predominantly buy prescription drugs directly from manufacturers and predominantly distribute them directly to healthcare providers. Nearly all of them (and all that have an interest in this case) are also registered with the U.S. Drug Enforcement Administration ("DEA") to distribute prescription drugs containing controlled substances (hereinafter "controlled prescription drugs"). These distributor members have a wide range of business models, including national and regional firms, and publicly traded and family-owned businesses. They include specialty distributors, firms that distribute only "biologics" (such as vaccines) or oncology drugs, firms that service only physician offices, and firms that distribute only generic products.

HDMA's members have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society. The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well-recognized over the years by Congress, DEA, HDMA and its members, and public health authorities.

HDMA's members are one of the principal groups of businesses affected by Congressional and DEA efforts to regulate the distribution of controlled prescription drugs. To assist the Court in reviewing the parties' respective actions

in this matter, HDMA respectfully provides the context in which DEA has taken enforcement actions against distributors while the agency has failed to provide meaningful guidance to assist the regulated industry in complying with DEA's interpretation of its implementing regulations. HDMA respectfully submits that despite the agency's oft-recited refrain that the regulations are "clear," the regulated industry doesn't know the rules of the road because they haven't been adequately explained.

DEA issued an Immediate Suspension Order ("ISO") against Cardinal Health based, in pertinent part, upon an alleged failure to maintain an effective program designed to detect and prevent diversion of controlled prescription drugs and an alleged failure to design and operate a system to detect and report suspicious orders as required by 21 C.F.R. §§ 1301.71 and 1301.74(b). HDMA's interest in this matter on behalf of its wholesale drug distributor members is this: a regime under which *any* wholesaler can summarily lose its DEA registration by an ISO *at any time* regardless of its programs to detect and prevent diversion of controlled prescription drugs and its systems to detect and report suspicious orders would constitute arbitrary and capricious decisionmaking by the agency and lack due process.

This case examines only the judgment of the court below in failing to preserve the status quo until the merits of DEA's administrative action against that registration can be decided in the Order To Show Cause proceeding. HDMA, however, wishes to express through this *amicus curiae* brief the grave concerns of the regulated industry that the process used by DEA in this matter, an ISO that deprives a wholesale distributor of the ability to distribute controlled prescription drugs prior to a hearing, is wholly inappropriate given the bare allegations of the ISO. DEA has placed a burden – discerning when diversion may occur beyond the DEA-registered and state-licensed prescribing practitioner and DEA-registered and state-licensed dispensing pharmacist – on wholesale distributors of controlled prescription drugs without providing meaningful guidance or tools that would enable the regulated industry to maintain compliance. Moreover, this regulatory liability shift is contrary to DEA's own regulations and policy regarding the responsibilities of practitioners and pharmacists to ensure that controlled prescription drugs are prescribed and dispensed only for legitimate medical purposes in the ordinary course of professional practice.

II. HDMA HAS UNDERTAKEN SIGNIFICANT EFFORTS TO OBTAIN GUIDANCE ON DIVERSION PREVENTION FROM DEA AND TO PROVIDE GUIDANCE TO ITS MEMBERS

HDMA has been engaged in extensive efforts to obtain guidance from DEA and has developed guidance for HDMA members on diversion prevention. In

2007, as DEA was issuing a series of letters to all distributor registrants, HDMA began a series of meeting requests to DEA's Office of Diversion Control to discuss what concrete steps HDMA members could take to maintain compliance with their statutory and regulatory obligations as registrants. As noted in papers accompanying Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction below, DEA met with HDMA on numerous occasions regarding diversion prevention. *See* Appendix A (Declaration of Joseph Rannazzisi, Attachment 2 to Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction, Case No. 1:12-cv-185 RBW, below (hereinafter "Rannazzisi Dec.")) at ¶ 37.

A. PUBLICATION OF HDMA'S INDUSTRY COMPLIANCE GUIDELINES

In late 2007, HDMA began development of its publication "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." Appendix B.[2] A committee of HDMA members contributed to the development of this publication. The Industry Compliance Guidelines ("ICG") contained the following elements:

I. Know Your Customer Due Diligence
II. Monitoring for Suspicious Orders
III. Suspend/Stop an Order of Interest Shipment

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[2] The Industry Compliance Guidelines have been available on HDMA's website since publication. http://hdmanet.org/gov_affairs/pdf_controlled/20081113_icg.pdf.

IV. Investigation of Orders of Interest
V. File Suspicious Order Reports With DEA
VI. Employees, Training and Standard Operating Procedures (SOPs)
VII. Additional Recommendations

The ICG was not crafted to be overly prescriptive; rather, it was designed to ensure that proper consideration was paid to the host of factors a wholesale drug distributor must face in evaluating orders for controlled prescription drugs. Under the ICG, when information indicates that further investigation is warranted, the first obligation is to look into the potential concern, not to drown DEA in a flood of suspicious order reports that may be otherwise explainable. The ICG also calls for documentation of procedures and their implementation and urges HDMA members to maintain robust compliance systems. Noteworthy elements include:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal standard operating procedures for compliance with 21 C.F.R. §§ 1301.71(a) and 1301.74(b) and any new DEA guidance, as well as employee training requirements/procedures; and
- Periodic review of the distributor's system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should be developed.

A draft of the voluntary guidance was presented to the DEA Office of Diversion Control and the DEA Office of the Chief Counsel in the spring of 2008 for their review and comment. The voluntary guidance was revised in light of DEA's comments and the current edition was published in the fall of 2008. On October 17, 2008, the DEA Chief Counsel wrote to HDMA, stating in pertinent part:

> The Drug Enforcement Administration (DEA) commends the efforts of the Healthcare Distribution Management Association (HDMA) to assist its membership to fulfill their obligations under the Controlled Substances Act and implementing regulations. The elements set forth in the "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" are important to sustaining effective controls to guard against diversion of controlled substances. . . .
>
> Although diversion control is not a "one size fits all" effort, companies that implement processes and procedures that effectively accomplish these objectives will do much to ensure that vital controlled substances are not diverted to illegitimate uses.

Appendix C.[3] HDMA has also held education sessions and numerous discussions on the Industry Compliance Guidelines.

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[3] Appendix C has been posted on the HDMA website since publication of the ICG. http://hdmanet.org/gov_affairs/pdf_controlled/20081113_dealetteronicg.pdf.

B. HDMA REQUESTS TO DEA FOR ARCOS DATA AND OTHER INFORMATION

In the District Court below, and in support of the Opposition to Plaintiff's Motion for Preliminary Injunction, defendants submitted the affidavit of the DEA Deputy Assistant Administrator for the Office of Diversion Control. That affidavit reads, in pertinent part:

> Customers ordering the same controlled substances from multiple distributors may be indicative of diversion due to the customer ultimately acquiring large amounts of controlled substances through multiple sources. Distributors are unable to access other distributor's [sic] information regarding distributions due to the proprietary nature of the information. The customer having multiple sources of distribution may avoid scrutiny by maintaining several sources to obtain controlled substances.

Rannazzisi Dec. (Appendix A) at ¶ 32. DEA, on the other hand, has access to this information because all distributors are required to report, relevant to this instant matter, distribution of Schedule II controlled substances and Schedule III narcotics directly to DEA under the Automated Reports and Consolidated Orders System (ARCOS). 21 C.F.R. § 1304.33.

HDMA respectfully submits that this information would be invaluable to distributors who are attempting to discern the *bona fides* of their customers. A customer receiving controlled substances from multiple sources would certainly be an appropriate subject of at least additional scrutiny. In February 2009 in a meeting with DEA's Office of Diversion Control, HDMA requested that

distributors be permitted access to aggregated ARCOS data so as to disclose whether any customers were receiving ARCOS-reportable controlled substances from multiple sources. When DEA asserted that such data contained proprietary information, HDMA indicated at that time that the requested data could be aggregated or otherwise masked to address concerns regarding proprietary information. While DEA responded that the agency was looking into the matter, it has not provided any such aggregated data.

Another meeting between HDMA and the Office of Diversion Control was held on December 7, 2010. HDMA reiterated its request for aggregated ARCOS data and sought to have DEA clarify its position on the agency's authority and willingness to respond to inquiries by registrants about customer ordering patterns based on information available to DEA. DEA indicated its concern that, even when aggregated, individual distributors' data might be identifiable and has not provided the requested data. *See* Appendix D (Summary of DEA-HDMA Meeting Held on December 7, 2010, *submitted as* Exhibit F to Cardinal Health's Motion for Preliminary Injunction, Case No. 1:12-cv-185 RBW, below).

After the December 2010 meeting, HDMA undertook a comprehensive assessment of member companies' questions and concerns with the current suspicious order monitoring requirements. On June 1, 2011, HDMA provided DEA with a series of questions seeking further guidance regarding concrete

suggestions for improving diversion prevention and HDMA's summary of the December 2010 meeting with DEA. Appendix E (June 1, 2011, HDMA letter to DEA, *submitted as* Exhibit E to Cardinal Health's Motion for Preliminary Injunction, Case No. 1:12-cv-185 RBW, below). Although there has been informal communication between HDMA and DEA regarding this course of correspondence, the agency has yet to answer HDMA's June 1, 2011, requests and questions.

III. IN THE ABSENCE OF APPROPRIATE GUIDANCE FROM DEA, REGISTRANTS FACE A COMPLIANCE BURDEN THAT IS IMPOSSIBLE TO MEET

HDMA wishes to underscore, in the strongest possible terms, its support for DEA's mission to prevent diversion of prescription controlled drugs. The societal costs of prescription drug abuse are huge, and the development and implementation of practices and procedures to detect and prevent diversion are burdens that HDMA members willingly bear. HDMA respectfully submits that the instant matter provides an object lesson that regardless of what diversion control programs a registered wholesale distributor may institute, DEA can summarily suspend the registration without adequate process.

In DEA's view, which was reiterated at the February 29, 2012, hearing below, the sheer volume of product reported to DEA under ARCOS should be indicative of diversion. This view does echo agency guidance from

December 2007: "The size of an order alone, whether or not it deviates from a normal pattern is enough to trigger the registrant's responsibility to report the order as suspicious." *See* Appendix A, Rannazzisi Dec. at ¶ 33 (quoting December 27, 2007 letter to registrants). While consistent, it is unhelpful. An order in a "normal pattern" is the antithesis of a "suspicious order."

DEA is requiring wholesale distributors to assume responsibilities while denying them the opportunity to make meaningful choices in fulfilling those responsibilities. Wholesale distributors cannot know, based upon any one factor, whether product that leaves their control is to be prescribed by DEA-registered and state-licensed practitioners and dispensed by DEA-registered and state-licensed pharmacists only for legitimate medical purposes.

DEA's reliance on volume as the touchstone for wholesale distributors is without merit. In DEA's own Policy Statement on Dispensing Controlled Substances for the Treatment of Pain, the agency abjures reliance on any single factor, including quantities of controlled substances prescribed, in determining whether prescriptions for controlled substances are "only for legitimate medical purposes in the usual course of professional practice." 71 Fed. Reg. 52,715, 52,720 cols. 2-3 (Sept. 6, 2006). Moreover, DEA's own regulations place the responsibility for lawful prescribing and dispensing of controlled substances on the two learned intermediaries who come after wholesale distributors in the supply

chain. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).

In a recent final order revoking a practitioner's registration, the DEA Administrator adopted the Chief Administrative Law Judge's finding that absolute and comparative statistical information regarding purchasing trends of Schedule II and Schedule III narcotics associated with the practitioner's practice, without context, was not probative of whether revocation was in order. *Carlos Gonzalez, M.D., Decision and Order*, 76 Fed. Reg. 63,118, 63,138, cols. 2-3 (Oct. 11, 2011) (final order revoking registration despite rejection of evidence as to volume).

Even if wholesale drug distributors wanted to review and assess a patient's medical information, including his or her pharmacy records of controlled substance prescriptions, it is not legally permissible for them to do so. In late 2000, the U.S. Department of Health and Human Services ("HHS"), pursuant to the authority granted by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), issued final regulations regarding "Standards For Privacy Of Individually Identifiable Health Information." 65 Fed. Reg. 82,462 (Dec. 28, 2000) (the "Privacy Rule").[4] The Privacy Rule applies to so-called "covered

[4] Those regulations were substantially revised nearly two years later. 67 Fed. Reg. 53,182 (Aug. 14, 2002).

entities," defined as: a health plan, a health care clearinghouse, or a health care provider that "transmits any health information in electronic form in connection with" a HIPAA-covered transaction. 45 C.F.R. § 160.103. Like physicians, pharmacists are deemed to be health care providers under HIPAA and are, therefore, covered entities. 42 U.S.C. §§ 1395x(s), (u).[5]

Covered entities are precluded from using or disclosing a patient's "protected health information" ("PHI") (*i.e.*, "individually identifiable health information") absent a patient's specific written "authorization," or in certain limited circumstances not relevant here. 45 C.F.R. § 164.502(a)(1); *see also* 45 C.F.R. § 164.506(a) and (c); 45 C.F.R. § 164.502(a)(1)(ii) ("[a] covered entity may not use or disclose protected health information, except . . . to carry out treatment, payment, or health care operations . . . ."). None of the relevant exceptions apply to a wholesale drug distributor fulfilling orders received from a retail pharmacy. There is therefore no basis upon which a wholesale distributor could obtain access to patient PHI through the pharmacy – its covered entity business partner.

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[5] *See also* U.S. Dept. of Health & Human Services, *Health Information Privacy*, available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html (accessed Feb. 21, 2012).

However serious a problem that prescription drug abuse is, the control of it cannot rest alone on the wholesale distributor that has neither the ability nor opportunity to review the individual patient or the practitioner's and pharmacist's interaction with that patient.

DEA's goal, the prevention of diversion of controlled prescription drugs, is, of course, a public good. HDMA and the regulated industry have been seeking, and will continue to seek, ways to work on this goal. The regulator, however, should not be permitted to sanction the regulated without a hearing based upon factors that the agency itself has previously found not to be determinative. HDMA readily acknowledges that law investigation and enforcement must be carried out in a manner that protects investigations and enforcement. At the same time, the government cannot be allowed to summarily act to shut down businesses without apprising the regulated industry of the rules which the government will use.

CONCLUSION

The district court erred in denying plaintiff-appellant Cardinal Health's motion for stay pending appeal. An injunction pending appeal should be granted pending Cardinal Health's appeal of the denial of its motion for preliminary injunction.

March 7, 2012 Respectfully submitted,

/s/
David L. Durkin
Richard L. Frank
OLSSON FRANK WEEDA TERMAN MATZ PC
600 New Hampshire Avenue, N.W.
Suite 500
Washington, D.C. 20037
(202) 789-1212
(202) 234-3550 (telecopy)
ddurkin@ofwlaw.com

Counsel to Movant/Proposed *Amicus Curiae*
Healthcare Distribution Management Association

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of March, 2012, I caused a copy of the foregoing *Amicus Curiae* Brief of the Healthcare Distribution Management Association to be served by hand on the following counsel of record in this case.

Douglas B. Farquhar
Delia A. Stubbs
Hyman, Phelps, & McNamara, P.C.
700 13th Street, NW
Suite 1200
Washington, DC 20005

Randolph D. Moss
Brian M. Boynton
Wilmer Cutler Pickering Hale
Dorr LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006

Counsel for plaintiff - appellant Cardinal Health, Inc.

Samantha L. Chaifetz
U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave., NW, Room 7238
Washington, DC 20530

Counsel for federal defendants- appellees

/s/
David L. Durkin